



DEPARTMENT OF HEALTH & HUMAN SERVICES

PUBLIC HEALTH SERVICE
NATIONAL INSTITUTES OF HEALTH

FOR US POSTAL SERVICE DELIVERY:

Office of Laboratory Animal Welfare
6700B Rockledge Drive, Suite 2500, MSC 6910
Bethesda, Maryland 20892-6910
Home Page: <http://grants.nih.gov/grants/olaw/olaw.htm>

FOR EXPRESS MAIL:

Office of Laboratory Animal Welfare
6700B Rockledge Drive, Suite 2500
Bethesda, Maryland 20817
Telephone: (301) 496-7163
Facsimile: (301) 480-3387

June 11, 2021

Re: Animal Welfare Assurance
A4051-01 [OLAW Case 1B]
Reference Case 1A

Dr. Wayne E. Cascio
Deputy Director, National Health and
Environment Effects Research Laboratory
U.S. Environmental Protection Agency
EPA-MD-B305-01, 109 T.W. Alexander Drive
Research Triangle Park, NC 27709

Dear Dr. Cascio,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your June 10, 2021 letter reporting an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at the US Environmental Protection Agency, following up on an initial telephone report on April 20, 2021. According to the information provided, OLAW understands that two sentinel rats were inadvertently sent to the cagewash area in their cage on a rack of dirty cages. The same issue had occurred previously, was reported to OLAW, the corrective actions were accepted, and the case was closed.

The animals were discovered by cagewash staff and were euthanized because they could not be returned to the housing area due to biosecurity concerns. Two new rats were deployed as sentinels for the room involved. The animal care contractor was in the process of reviewing and implementing changes to operating procedures following the first incident. The corrective actions consisted of continuing the review being conducted by contract management. Biweekly meetings are underway with the contractor and animal facility officials, external subject matter experts were retained, and plans are being updated to ensure appropriate management oversight and quality assurance. The contractor replaced the animal facility project manager with a new individual. The contractor's performance will be intensively monitored and the overall contract will be recompeted soon.

Based on its assessment of this explanation, OLAW understands that measures are underway to correct and prevent recurrence of this problem. OLAW concurs with the actions taken by the institution to comply with the PHS Policy. Feel free to update OLAW on the status of the contract and satisfaction with meeting animal care expectations if major changes are undertaken in the future. Thank you for keeping OLAW apprised on this matter.

Sincerely,

Axel Wolff, M.S., D.V.M.
Deputy Director
Office of Laboratory Animal Welfare

cc: IACUC Chair



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
CENTER FOR PUBLIC HEALTH AND ENVIRONMENTAL ASSESSMENT
Research Triangle Park, NC 27711

OFFICE OF
RESEARCH AND DEVELOPMENT

June 10, 2021

Axel Wolff, M.S., D.V.M.
Deputy Director
Office of Laboratory Animal Welfare
National Institutes of Health

Dear Dr. Wolff:

We are writing to report final resolution of an adverse animal welfare incident at the US EPA Research Triangle Park (RTP) research program (Assurance # D16-00569 (b) (6)), including measures taken by the program to ensure that such events will not be repeated. A preliminary report of this event was originally called in to you at OLAW by the Director of our Animal Resources Program Office on Monday, April 19, 2021.

On the morning of April 19, 2021, routine cage changes were performed on pair-housed rats by animal care staff. In this process rats are transferred from used, soiled bedding and cages on one rack to a new rack with clean cages containing new bedding and enrichment, and the cage card and its holder are transferred with the rats. However, on this date, two adult female rats of a socially housed pair of rats used for sentinel monitoring of pathogens were accidentally left behind in the dirty cage, with their cage card, along with other empty dirty cages on its rack, and the entire rack with the two rats was rolled to the cage wash room on a different floor of the animal facility. All other animals on this rack were moved to clean cages on a new rack. The rats were discovered in their home cage prior to dumping soiled bedding and retained in that cage while the rest of the equipment was cleaned. The rats could not be returned to the colony because they had travelled from a clean holding room to a locale outside the clean area (the cage wash area), and consequently they were humanely euthanized. Their tissues were utilized for the sentinel pathogen program. While these sentinel animals were used for their intended purpose, they were euthanized well before their scheduled time. Additional rats were deployed for this holding room to replace the lost sentinel animals.

On April 15, 2021, we provided a final report to OLAW regarding an incident occurring on April 12, 2021 with nearly the exact same circumstances, where a rat was mistakenly taken to the cage wash room (A4051-01, OLAW Case 1A, Reference Case 1B, acknowledged by OLAW on April 23, 2021). That incident resulted in the termination of a contract animal caretaker (a joint decision of the prime contractor and subcontractor, not influenced by the US EPA), and an in-depth review by the US EPA Contracting Officer (CO) of the contract's performance, inclusive of terrestrial animal care, aquatic animal care, veterinary care, facility maintenance, and

provisioning of the facility. The review and implementation of changes to operating procedures to ensure that the quality of animal care meets contractual requirements was not completed prior to the occurrence of the second incident (seven days after the first incident). Even though the review and procedural changes were not yet complete, we at the US EPA are quite dismayed that this situation could have occurred again.

The animal care contractor was immediately informed of the situation, and contract management continued its investigations, including contractual mechanisms used to ensure that quality of animal care meets contractual requirements.

- The Animal Resources Program Office (ARPO), CO, prime contractor, and subcontractor are continuing biweekly meetings to ensure that an Action Plan and updated operating procedures addressing the deficiencies in animal care are successfully implemented.
- External experts, including a management auditor and an aquatics specialist, were consulted.
- Updated plans emphasize the importance of management oversight and quality assurance in addition to individual staff performance.
- As a result of the investigation, audits, and internal actions, the prime contractor elected to replace the animal facility project manager at the RTP campus, effective on June 8, 2021. A new project manager had already been identified and EPA began the contract intake process for that individual on June 9, 2021. An interim chain of command was put in place immediately upon the first manager leaving the facility.

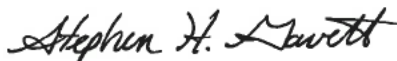
At this stage, the US EPA is satisfied that necessary and sufficient corrections are being implemented to ensure quality management of animal care to prevent any future occurrences of this nature. The ARPO and CO will continue to intensively monitor contract performance. The current contract is in an extension and the entire contract will be recompleted over the next few months. Past performance will be taken into consideration during that recomplete.

We hope these measures satisfactorily address the issues raised by this incident. Please contact Stephen Gavett (b) (6) Gavett.stephen@epa.gov) or Jaimie Graff (b) (6) Graff.jaimie@epa.gov), Animal Resources Program Office, if you have further questions.

Sincerely,



Wayne E. Cascio, M.D.
Director, CPHEA
Institutional Official



Stephen H. Gavett, Ph.D., D.A.B.T.
CPHEA / PHITD / CIB
IACUC Chair

Wolff, Axel (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Friday, June 11, 2021 7:11 AM
To: Graff, Jaimie
Cc: OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: Report of noncompliance Assurance # D16-00569

Thank you for this report. We will respond soon.
Axel Wolff

From: Graff, Jaimie <Graff.Jaimie@epa.gov>
Sent: Thursday, June 10, 2021 3:15 PM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Cc: Cascio, Wayne <Cascio.Wayne@epa.gov>; Baghdikian, Christina <Baghdikian.Christina@epa.gov>; (b) (6)
(b) (6) (b) (6) Gavett, Stephen
<Gavett.Stephen@epa.gov>; Graff, Jaimie <Graff.Jaimie@epa.gov>; (b) (6)
(b) (6) Jarrell, Leslie <Jarrell.Leslie@epa.gov> (b) (6)
(b) (6)
Subject: Report of noncompliance Assurance # D16-00569

Good afternoon;
Attached please find a final report of noncompliance.
This report also follows up on commentary from Dr. Wolff's final response to OLAW Case A4051-1A
Please call or email me if you have any questions.
Thank you;
Jaimie

Jaimie Graff, MA, CPIA | Director, Animal Resources Program Office | US EPA/ORM/RSCD/FRCB | Phone: (b) (6)
Cell: (b) (6)



Initial Report of Noncompliance

By: (b) (6)

Date: 4/20/21

Time: 9:30

Name of Person reporting: Jamie Gray

Telephone #: (b) (6)

Fax #:

Email:

Name of Institution: US EPA

Assurance number: A4051

Did incident involve PHS funded activity? _____

Funding component: _____

Was funding component contacted (if necessary): _____

What happened?

2 sentinel rats sent to cagewash in rack
 Staff not following SOP

Species involved: Rats

Personnel involved:

Dates and times:

Animal deaths:

Projected plan and schedule for correction/prevention (if known): _____

Discipline staff

Projected submission to OLAW of final report from Institutional Official:

OFFICE USE ONLY

Case # _____

See also Case A4051-1A